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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/669,104	09/25/2000	Walid Najib Aboul-Hosn	0261-16761-DIV	7836

7590 08/26/2003  
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Milwaukee, WI 53226

EXAMINER

MACHUGA, JOSEPH S

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/669,104

Applicant(s)

ABOUL-HOSN, WALID NAJIB

Examiner

Joseph S. Machuga

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s): \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other:

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-4 and 12-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 12 both states that the portal is formed in either a blood vessel or heart valve. The alternative language makes the claims indefinite.

#### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claim 5 and 12 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Orejola #4985014.

#### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3762

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 6, 7, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orejola 4985014 in view of Hall #4946440 and Buckberg et al #5013296.

Orejola discloses a heart pump having two coaxial conduits for receiving and returning blood. The conduits are positioned within the heart by a balloon 48. The reference notes in column 1 lines 35-42 that the device is introduced into a paralyzed heart, inferring the use of a cardiopulmonic compound. Not disclosed by this reference is a balloon catheter having perforations to introduce a medication/coolant.

Buckberg et al teaches that it's old and well known to feed a cooled cardiopulmonic solution to the heart during a medical procedure to stop the heart.

Hall teaches that it is old and well known to add perforations to a balloon catheter to feed material to the heart or vein. The design presented in this patent helps reduce contamination.

Given these references it would have been obvious to one of ordinary skill in the art to add a feed for a cooled cardiopulmonic to Orejola's device given Orejola's disclosure that the heart should be paralyzed during the introduction of the device and Buckberg's teaching that a cooled cardiopulmonic material to perform this function is old and well known.

in the art. To feed the material in through a perforated balloon catheter would have been obvious given Hall's teaching that such a design helps reduce contamination.

4. Claims 8-11 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orejola in view of Hall and Macoviak #5738649.

Orejola discloses a heart pump having two coaxial conduits for receiving and returning blood. The conduits are positioned within the heart by a balloon 48. The reference notes in column 1 lines 35-42 that the device is introduced into a paralyzed heart, inferring the use of a cardiopulmonic compound. Not disclosed by this reference are the multiple balloon catheters having perforations to introduce a medication/coolant.

Hall teaches that it is old and well known to add perforations to a balloon catheter to feed material to the heart or vein. The design presented in this patent helps reduce contamination.

Macoviak discloses a catheter for use in heart surgery. For operations on the left heart regions the reference teaches adding multiple inflatable balloons located downstream of the aortic valve and upstream of the mitral valve. The reference also teaches using a coolant and a cardiopulmonic compound.

Given these references it would have been obvious to one of ordinary skill in the art use multiple balloons in Orejola's device located downstream of the aorta and upstream of the mitral valve when working on the left heart region as taught by Macoviak. To use perforations in the balloons to feed material such as a coolant/cardiopulmonic would have been obvious given Hall's teaching that this arrangement reduces contamination.

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sweezer et al (5478309) and Runge (5688245) are cited to show related systems. Yamazaki (5147388) and Booth et al (5820586) are cited to show secured conduits. Mische (5792106, Leone (5674198), Buras (4693243) and Shapland et al (5286254) are cited to show perforated balloons. Lee (6176844), Siess et al (5911695) and Wampler (4625712) are cited to shown related pumps. Boyles (5167628) is cited to show a multiple balloon catheter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Machuga whose telephone number is 703-305-6184. The examiner can normally be reached on Monday-Friday; 6:30-3:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D Sykes can be reached on 703-308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are 703-306-4520 for regular communications and 703-306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

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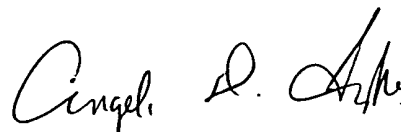
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Joseph S. Machuga  
Examiner  
Art Unit 3762

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August 10, 2003



ANGELA D. SYKES  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700